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Sertifikaat

REPUBLIEK VAN SUID-AFRIKA

Certificate

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PATENT OFFICE

DEPARTEMENT VAN HANDEL EN NYWERHEID

REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF TRADE AND INDUSTRY

Hiermee word gesertifiseer dat
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4

the documents attached hereto are true copies of the Forms P2, P6, provisional specification and drawings of South African Patent Application No. 99/2146 filed in the name of DESIGNODEV LIMITED, subsequently assigned to DUGMORE, Peter Balfour; BULL, Anthony Eric; REYNOLDS, Stanford William Gladwin.

09/936810

Filed	:	17.03.99
Entitled	:	A SAFETY ASSEMBLY FOR A HYPODERMIC APPLICATOR SET

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH
RULE 17.1(a) OR (b)

Geteken te PRETORIA in die Republiek van Suid-Afrika, hierdie 12th dag van April 2000
in the Republic of South Africa, this day of

Registrateur van Patente
Registrar of Patents

FORM P.2

REPUBLIC OF SOUTH AFRICA	REGISTER OF PATENTS	PATENTS ACT,

OFFICIAL APPLICATION			LODGING DATE: PROVISIONAL		ACCEPTANCE DATE	
21	01	992146	22	17.03.99	47	
INTERNATIONAL CLASSIFICATION			LODGING DATE: COMPLETE		GRANTED DATE	
51			23			

FULL NAME(S) OF APPLICANT(S)/PATENTEE(S)

71 DESIGNODEV LIMITED

AANSOEKERS VERVANG
APPLICANTS SUBSTITUTED

APPLICANTS SUBSTITUTED:	DATE REGISTERED
71 DUGMORE: Peter B; BULL, Anthony E. REYNOLDS: Stanford William G.	16.3.2000

ASSIGNEE(S)	DATE REGISTERED
71	

FULL NAME(S) OF INVENTOR(S)

72 PETER BALFOUR DUGMORE; ANTHONY ERIC BULL; STANFORD WILLIAM GLADWIN REYNOLDS

PRIORITY CLAIMED	COUNTRY	NUMBER	DATE
N.B. Use International abbreviation for country (see Schedule 4)	33 NIL	31 NIL	32 NIL

TITLE OF INVENTION

54 A SAFETY ASSEMBLY FOR A HYPODERMIC APPLICATOR SET

ADDRESS OF APPLICANT(S)/PATENTEE(S) 4 Swanmore Rd. Rondebosch.
31 Grotto Rd. Rondebosch
~~LA MOTTE CHAMBERS, ST HELIER, JERSEY JE1 1BJ, CHANNEL ISLANDS~~
18 Hopson Rd. Westville Kwazulu-Natal

ADDRESS FOR SERVICE	S AND F REF
74 SPOOR AND FISHER, SANDTON	JP/D 1573/jw

PATENT OF ADDITION NO.	DATE OF ANY CHANGE
61	

FRESH APPLICATION BASED ON	DATE OF ANY CHANGE

SPOOR AND FISHER

REPUBLIC OF SOUTH AFRICA REVENUE — FORM P.1

REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978
APPLICATION FOR A PATENT
AND ACKNOWLEDGEMENT OF RECEIPT
(Section 30 (1) – Regulation 22)

17.03.99

R 060,00

The granting of a patent is hereby requested by the undermentioned applicant on the basis of the present application filed in duplicat

REPUBLIC OF SOUTH AFRICA INKOMSTE DIENS

OFFICIAL APPLICATION NO.			APPLICANT'S REFERENCE
21	01	992146	JP/D 1573/jw

FULL NAME(S) OF APPLICANT(S)

71	~~DESIGNODEV LIMITED~~ DUGMORE, Peter B; BULL Anthony E; REYNOLDS Stanley W.G. 16-3-2000

AANSOEKERS VERVANG APPLICANTS SUBSTITUTED

ADDRESS(ES) OF APPLICANT(S)

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TITLE OF INVENTION

54	A SAFETY ASSEMBLY FOR A HYPODERMIC APPLICATOR SET

THE APPLICANT CLAIMS PRIORITY AS SET OUT ON THE ACCOMPANYING FORM P.2 THE EARLIEST PRIORITY CLAIM IS:

COUNTRY:	NUMBER:	DATE:
NIL	NIL	NIL

THIS APPLICATION IS FOR A PATENT OF ADDITION TO PATENT APPLICATION NO.

21	01	

THIS APPLICATION IS A FRESH APPLICATION IN TERMS OF SECTION 37 AND IS BASED ON APPLICATION NO.

21	01	

THIS APPLICATION IS ACCOMPANIED BY:

- ☒ 1. A single copy of a provisional specification of 11 pages.
- ☒ 2. Drawings of 5 sheets.
- ☐ 3. Publication particulars and abstract (Form P.8 in duplicate).
- ☐ 4. A copy of Figure ..... of the drawings (if any) for the abstract.
- ☐ 5. An assignment of invention.
- ☐ 6. Certified priority document(s) .....
- ☐ 7. Translation of the priority document(s).
- ☐ 8. An assignment of priority rights.
- ☐ 9. A copy of the Form P.2 and the specification of S.A. Patent Application No.
- ☐ 10. A declaration and power of attorney on Form P.3.
- ☐ 11. Request for ante-dating on Form P.4.
- ☐ 12. Request for classification on Form P.9.
- ☒ 13. Form P.2 in duplicate.

74 ADDRESS FOR SERVICE: SPOOR AND FISHER, SANDTON

Dated: 17.03.99

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PATENT ATTORNEYS FOR THE APPLICANT(S)

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REGISTRAR OF PATENTS, DESIGNS, TRADE MARKS AND COPYRIGHT
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1999 -03- 17
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FORM P.6

REPUBLIC OF SOUTH AFRICA
PATENTS ACT, 1978

PROVISIONAL SPECIFICATION

(Section 30(1) – Regulation 27)

OFFICIAL APPLICATION NO.		LODGING DATE	
21 01	992146	22	17.03.99

FULL NAME(S) OF APPLICANT(S)

71	~~DESIGNODEV LIMITED~~ DUGMORE: Peter B. BULL: Anthony Eric. REYNOLDS: Stanford W.G. ~~AANSOEKERS VERVANG~~ APPLICANTS SUBSTITUTED

FULL NAME(S) OF INVENTOR(S)

72	PETER BALFOUR DUGMORE; ANTHONY ERIC BULL; STANFORD WILLIAM GLADWIN REYNOLDS

TITLE OF INVENTION

54	A SAFETY ASSEMBLY FOR A HYPODERMIC APPLICATOR SET

BACKGROUND OF THE INVENTION

THIS invention relates to a safety assembly for a hypodermic applicator set, and in particular to a safety assembly for a hypodermic cannula set.

The needles of used syringes and cannula infusion and fluid extraction sets pose an increasing threat to the transmissibility of potentially lethal infections such as HIV^+ and hepatitis B viruses to persons handling the devices both during and after use.

In the recent past, a vast array of devices and systems for preventing contact with used needles of medical devices have been proposed. These include syringes and cannula devices extending to protecting shields or sheaths into which the devices are withdrawn after use to a position where the needle point is shrouded from accidental contact. Such shielding devices have tended to focus on syringe sets as opposed to cannula sets, in spite of the fact that the latter constitute a greater risk in view of the greater quantities of potentially contaminated blood involved and the generally jerkier movements associated with the necessity to withdraw the needle quickly from the cannula catheter and to prevent blood emission or fluid spillage while simultaneously connecting a fluid infusion or extraction tube to the catheter.

In the case of both syringe sets and cannula sets, the additional operating length of the device constituted by the protecting shield, and the additional components in the retraction mechanism employed, have contributed both to significant additional manufacturing costs and also to user inconvenience.

It is an object of the invention to provide a safety assembly for a hypodermic cannula set in which the risk of needle stick is minimized after the needle has been in contact with potentially infected blood, which is economical to produce and which is simple and convenient to use.

SUMMARY OF THE INVENTION

According to the invention there is provided a safety assembly for a hypodermic applicator set comprising a needle assembly including a needle seat from which a needle extends, an elongate retractor which is mountable to the needle seat, a safety shield for housing the needle assembly slidably within a chamber defined therein and having a front end through which the needle is arranged to project and a rear open end through which the elongate retractor extends, and at least one retaining formation carried on the shield, the needle assembly being moveable between an extended position in which the needle extends through the front end of the shield and a retracted position in which the needle is withdrawn by the retractor to be safely held captive within the chamber by the retaining formation.

Preferably, the retractor is detachably mountable to a rear end of the needle seat and is separable from the needle seat when in the retracted position.

Conveniently, the needle extends through a spigot defining a finger barrier at the front end of the safety shield, and a cannula catheter is detachably mountable to the spigot.

Preferably, the hypodermic applicator set is a hypodermic cannula set.

Typically, a needle shield is fitted over the needle and catheter when in the extended position, the needle shield being mountable to a front end of the safety shield or retractor.

In a preferred form of the invention, detent means are provided for detaining the needle assembly in the extended position prior to use, the detent means preferably being incorporated on the retractor and the needle shield.

Preferably, the needle shield and the retractor carry complemental engaging formations constituting the detent means for detachably engaging one another when the safety assembly is in the stowed position.

Conveniently, a sealing plug is located towards the front end of the chamber for preventing the leakage of fluid from the catheter into the chamber, the needle extending in use through the sealing plug in the extended position and being withdrawable back through the sealing plug to the retracted position in which the sharp end of the needle is seated rearwardly of the sealing plug, the sealing plug being arranged to reseal on withdrawal of the needle.

Advantageously, the sealing plug serves as a front retaining formation for preventing the needle from escaping through the front end of the safety shield when in the retracted position.

The retractor typically includes a pair of outer caliper arms which are slidably engageable with an outer surface of the safety shield and which are formed with finger-engaging formations, and a central shaft or plunger which extends into the chamber and terminates in a needle seat engaging formation serving as the detent means.

Advantageously, the needle seat defines a viewing chamber for monitoring the ingress of fluid via the needle, and a fluid retaining means such as a filter disc is mounted at a rear end of the viewing chamber, the filter disc being held in position by the needle seat engaging formation at a front end of the plunger.

The invention extends to a method of manufacturing a safety assembly for a hypodermic applicator set comprising the steps of providing a safety shield having a front spigot end and a rear open end, fitting a catheter to the front spigot end of the safety shield, loading a needle assembly, which includes a needle projecting from a needle seat, through the rear open end of the shield, and driving the needle assembly into an extended position in which the needle extends through the catheter using a retractor having a central plunger or shaft which detachably engages a complemental formation at a rear end of the needle seat.

Preferably, the method includes the further steps of fitting a needle shield over the needle and catheter, with a rear end of the needle shield detachably engaging a front end of the retractor.

Conveniently, the method includes the further steps of fitting a sealing disc to the needle by piercing a sheet of disc-forming material with the needle, and using the needle as a centering axis for punching or cutting out the sealing disc.

The assembly steps preferably take place on a carousel having a plurality of stations, at which the various components are up- or downloaded.

The invention extends to apparatus for manufacturing and assembling the safety assembly using the above method.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a perspective view of a cannula safety assembly of the invention in a stowed configuration prior to use;

Figure 2 shows a partly cross-sectional side view of the cannula safety assembly of Figure 1 just prior to use with the needle shield removed;

Figure 3 shows a partly cutaway side view of the cannula safety assembly of Figure 2 in the retracted safe position;

Figure 4 shows a detailed cross-sectional side view along the lines 4-4 of Figure 1;

Figure 5 shows a detailed cross-sectional side view of part of the needle and viewing chamber assembly in the retracted position;

Figure 5A shows an end-on rear view of the viewing chamber of Figure 5;

Figure 6 shows a perspective view of a retractor forming part of the cannula safety assembly of the invention;

Figures 7A to 7D show partly schematic diagrams of various steps in the manufacturing process whereby a sealing plug is fitted to the needle;

Figures 8A & 8B show respective partly schematic top plan and rolled out side views of various steps in an automated assembly sequence adopted during the manufacturing process.

DESCRIPTION OF EMBODIMENTS

Referring first to Figures 1 to 3, a cannula safety assembly 82 includes a round cylindrical cannula safety shield 84 having a rear open end 85, an elongate retractor 86 which fits over the safety shield 84, and a needle assembly 88 which locates within the safety shield 84 when in the retracted Figure 3 position. A cannula catheter 90 is formed with a rear hollow seat portion 92 which locates in a friction fit over a spigot 94 defined at the front end of the safety shield 84. A needle cover or shield 96 is in turn fitted over the front end of the safety shield, providing a protective cover for the needle assembly 88 and cannula catheter 90 when in the extended position.

The retractor 86 is provided with a central shaft or plunger 98 which extends through the rear open end 85 of the safety shield and terminates in a balled end 100. A pair of caliper arms 102 extend in a direction parallel to the central shaft 98, and have opposed complemental concave faces 103 which allow them to fit snugly around the safety shield, as is clear from Figure 6.

Figures 4 and 5 show clearly how the various components described above fit together when assembled. The needle assembly 88 comprises a needle 106 fitted to a transparent needle seat 108, which also defines a viewing chamber 110. A filter disc 112 is fitted against a shoulder 114 at a rear end of the chamber, and is held in position by the balled end 100 of the shaft, which in turn locates within a complemental socket-defining channel 116 located

towards the rear of the needle assembly. A rubber sealing plug 118 is located snugly within the safety shield just rearwardly of the spigot 94. The sealing plug 118 is retained in position by means of a circumferential retaining rib 120 having a shallow sawtooth profile.

The needle and catheter shield 96 is dimensioned to slide snugly over the front end of the safety shield. A clip-receiving recess 122 is formed at the rearmost end of the needle shield 96, and is arranged to accommodate complemental clips 124 extending from the front end of the retractor calipers 86 when in the stowed position. The needle shield 96 and the retractor 86 thus mate with one another in a click fit to hold the entire assembly firmly together.

In use, the cannula safety assembly 82 is operated as follows. Finger pressure is applied inwardly against the opposed flexible finger grips 126 at the ends of the caliper arms 102, and the needle shield is then pulled off as the clips 124 are released from the clip-receiving apertures 122. The cannula safety assembly is now in its Figure 2 condition, at which stage the practitioner grips the cannula safety assembly around the finger grips 126 and introduces the sharp end 128 of the needle into the vein. Once the cannula catheter 90 is in place in the vein, which is indicated by the backflow of blood into the viewing chamber 110, the practitioner grips the front end 130 of the safety shield to prevent the cannula catheter from dislodging, and withdraws the retractor 86 with the other hand via the finger grips 126. The needle assembly 88 is retracted to the Figure 3 position in which the aperture formed by the needle 106 through the rubber sealing plug 118 seals off, so as to prevent the continued backflow of blood into the safety shield.

A retaining rib 132 extending inwardly from the rear end of the shield serves to hold the needle assembly 88 captive within the chamber by abutting against a

rearmost disc-shaped castellated flange 134 formed at the rearmost end of the needle assembly. The flange forms a snug sliding fit with the inner wall 136 of the safety shield, and is provided with six evenly spaced breather gaps 140 for ensuring that a vacuum is not formed in the space 141 between the needle assembly 88 and the shield 82. The retaining rib 132 is formed with an inner retaining wedge 142 against which the flange 134 locates. Further rearward force on the retractor causes the ball 100 to break away from the socket 116. During breakaway of the ball 100, additional outward pressure is exerted on the flange 134, thereby ensuring that the flange 134 is retained firmly in position behind the rib 132. The porous membrane 112, which was previously mechanically locked in position by the front face of the ball 100, is now retained by a rear shoulder 138 to prevent blood from escaping from the viewing chamber 110. The provision of both the sealing plug 118 and the filter disc 112 allow the practitioner to have sufficient time to arrange for a fluid line to be connected, without being concerned about the uncontrolled backflow of fluid through the catheter. The combination of the air permeable filter disc 112 and breather gaps defined by flat faces 148 on either side of the ball 100 provide an air escape path as blood is introduced into the viewing chamber 110.

Referring now to Figures 7A to 7D, the various manufacturing steps involved in locating the disc-shaped sealing plug 118 concentrically over the needle 106 are shown. The needle assembly 88 stops at a sealing plug station 149, where a sheet of sealing plug rubber 150 is located between a die and punch assembly comprising a pair of apertured dies 152A and 152B and a circular punch 153. The needle is positioned in such a way that it is co-axial with the axis 154 defined by the die apertures. The needle is then clamped into position by means of a pair of clamps 156, after which the punch and die assembly is moved to the right, thereby causing the needle to pierce the strip of sealing plug material 150. The sealing plug material 150 is flexible, and re-aligns itself with

the needle, whereafter the punch 153 moves to the right to cut the sealing plug 118, which is now concentrically located on the needle in the correct axial position along the needle. The punch then retracts, the needle moves on, and the strip of sealing plug material 150 indexes to the next position.

The various steps involved in the manufacture and insertion of the filter disc 112 are similar to those involved in manufacturing and placing the sealing plug, in that a die and punch assembly is used to punch filter discs from an indexed sheet of filter disc material, with the punch being arranged to locate the filter disc in the appropriate position within the viewing chamber.

Figures 8A and 8B illustrate the manner in which the cannula safety assembly is manufactured in a fully automated manufacturing procedure. The entire assembly procedure takes place on a carousel 160 which rotates relative to a barrel or safety shield loading station 162, a catheter loading station 164, a needle assembly loading station 166, a retractor loading station 168, a retractor inserting station 170 and a needle shield loading station 172. The completed assembly is rotated through one more step before being released for packaging at a packaging station 174. For ease of reference, the various stations have also been numbered from 1 to 8.

Referring now to Figure 8B, at the shield loading station 162, cannula safety shields 84 are drop loaded and then clamped in position. A string of catheters 90 is then drop loaded, with each catheter then being individually uploaded from the drop tube or bandoleer via a reciprocating ram arrangement 176. At the needle loading station 166, a string of needle assemblies is then sequentially drop loaded into the rear open end of each needle shield 84. The needle assemblies are pre-fitted with the sealing plugs 118 and filter discs 112 in the manner described earlier on in the specification. At the retractor loading station

168, the central shafts or plungers 98 of a string of retractors 86 are drop loaded into the rear end of each needle shield 84. At the retractor inserting station 170, the retractor shaft 98 is inserted completely into the safety shield 84 by a plunger 178, thereby pushing the needle assembly through the safety shield to the Figure 2 extended position, with the ball 100 of the retractor holding the filter disc 112 in position.

At the needle shield loading station 172, the string of needle shields 96 is initially downloaded, and is then uploaded from a drop tube or bandoleer, with a ram 180 serving to urge the needle shield 96 into position in which it forms a click fit with the end of the retractor in a manner previously described. The complete cannula safety assembly 82 is then conveyed to the packaging station 174.

It is clear from the above that the cannula safety assembly of the invention lends itself readily to a high speed automated manufacturing and assembly process. This process is further speeded up by virtue of the fact that the entire assembly is mechanically fitted together, with no adhesives or bonding agents being required in the manufacturing process apart from the bonding of the needle to the needle seat.

It will also be apparent that because the rear of the needle assembly 88 in the safe position is substantially flush with the rear of the cannula safety shield 84, the overall length of the safety shield necessary to shroud the needle point 128 in the safe position approximates closely the overall length of the needle assembly – in practice, generally of the order of no more than 50mm.

DATED THIS 17TH DAY OF MARCH 1999

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Fig 1

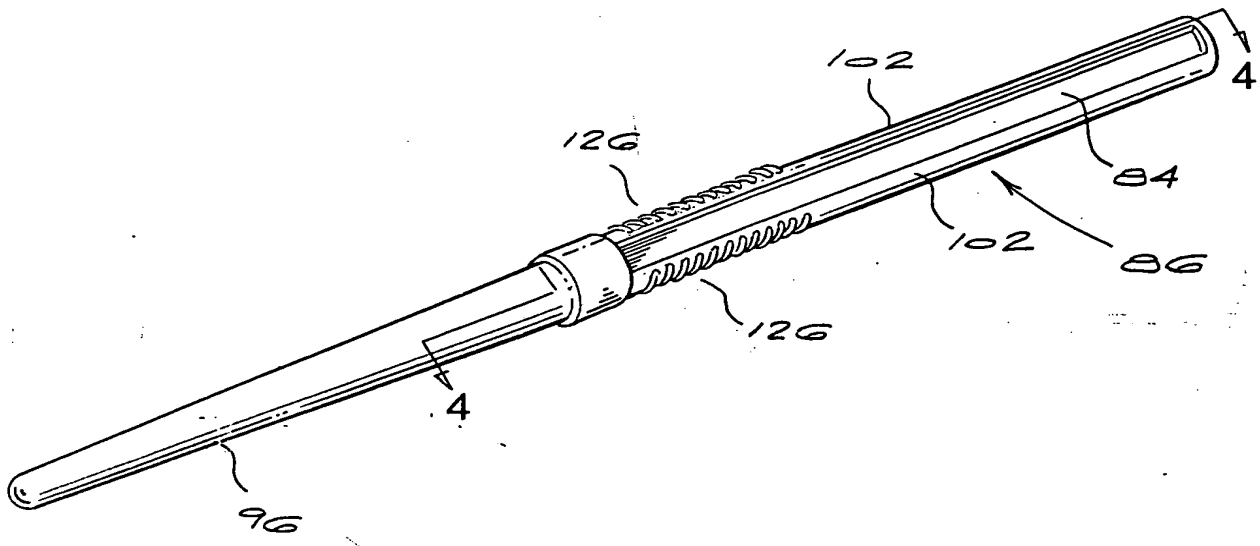

Fig 2

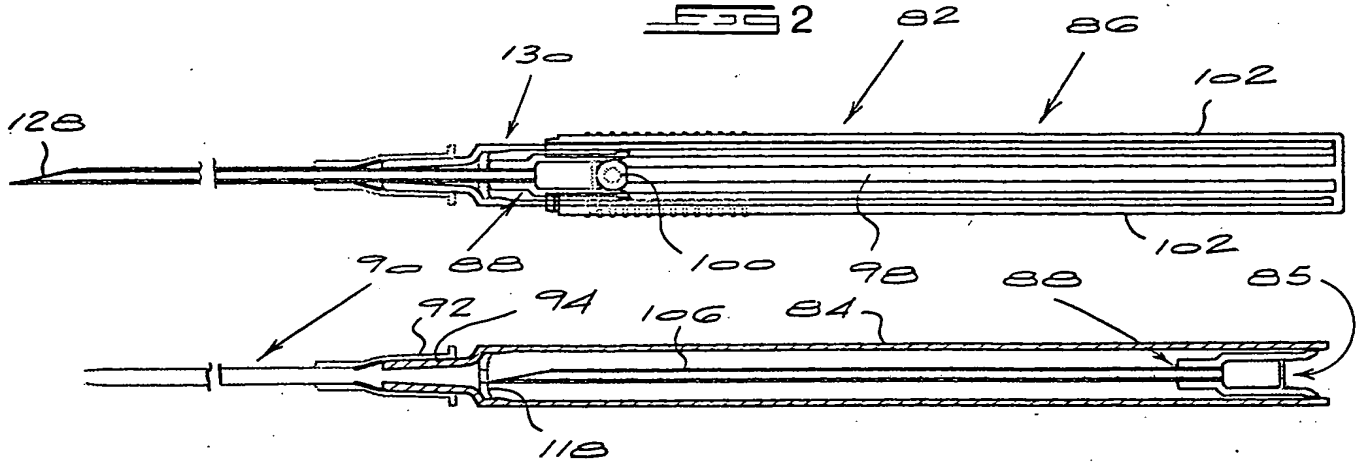

Fig 3

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FIG 4

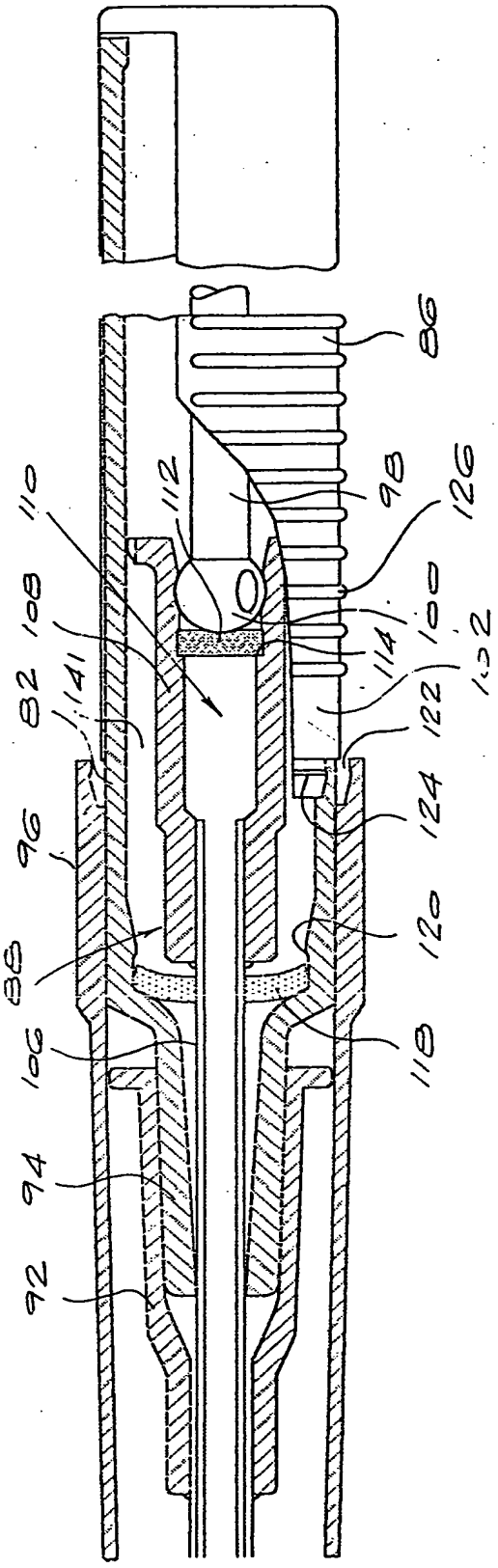

FIG 5

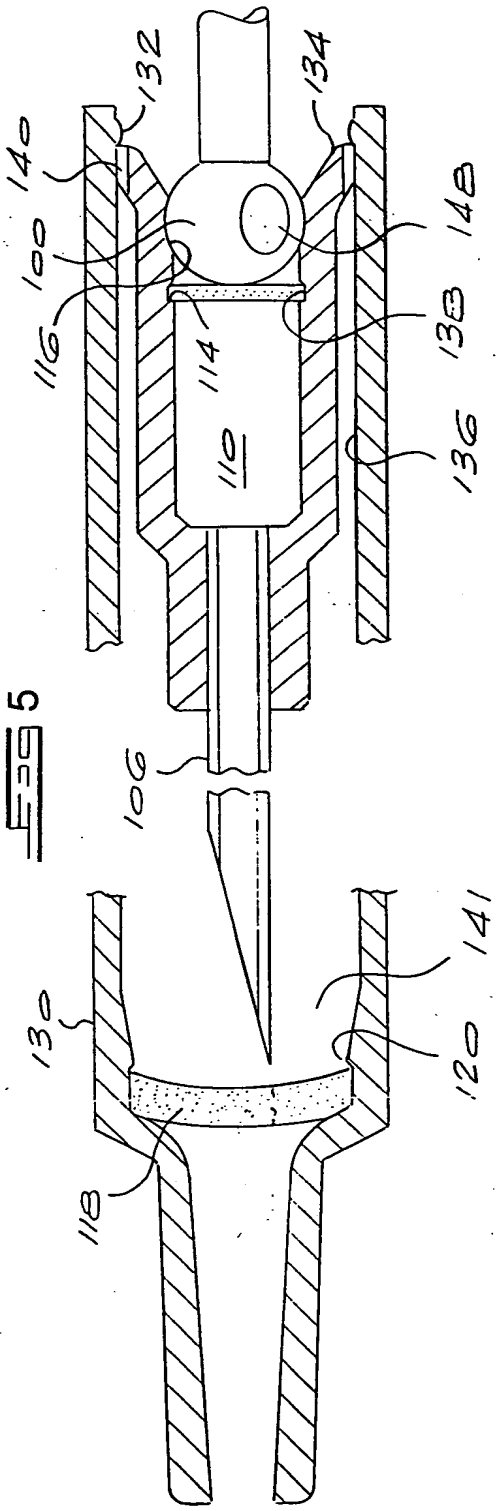

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FIG 5A

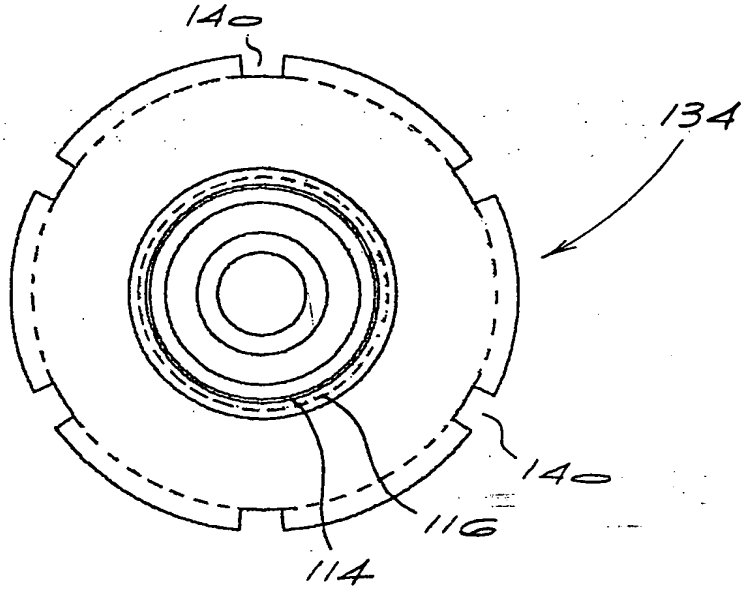
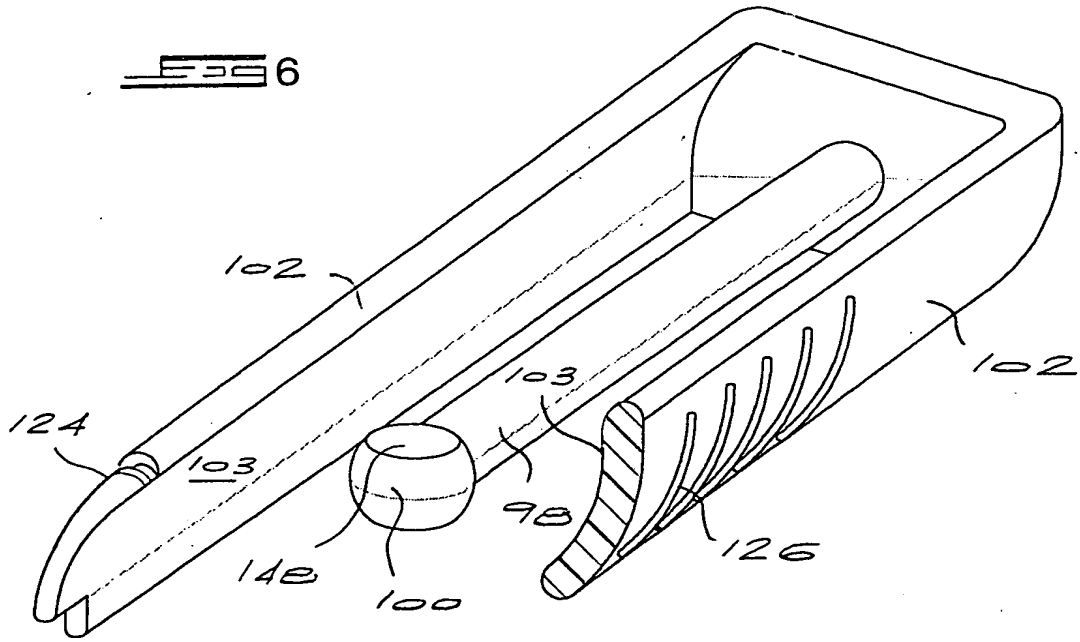


FIG 6



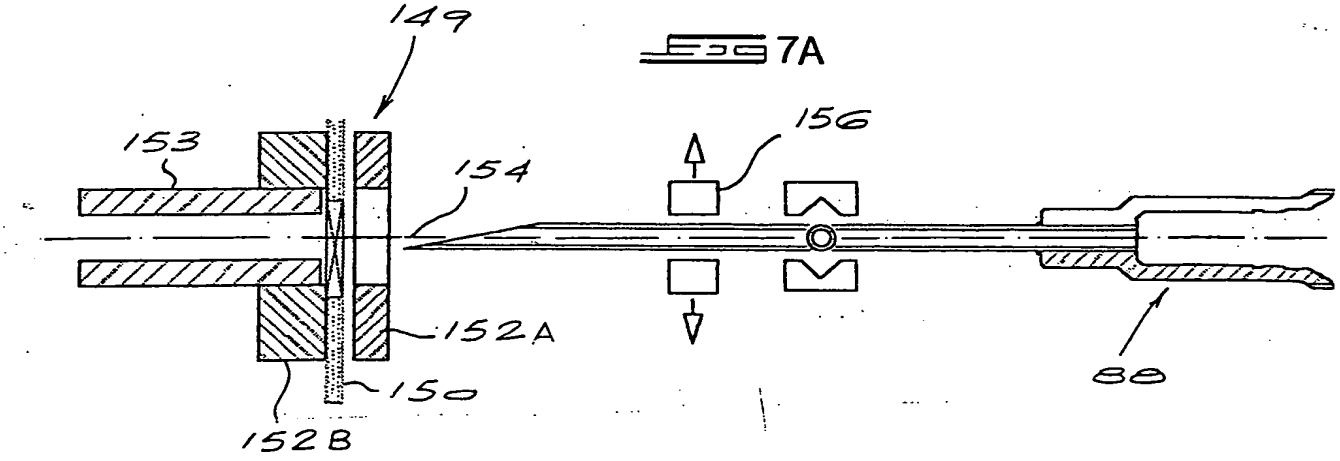


FIG 7A

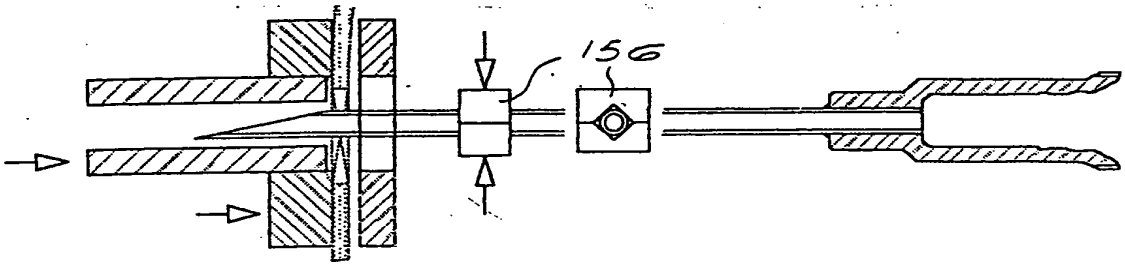


FIG 7B

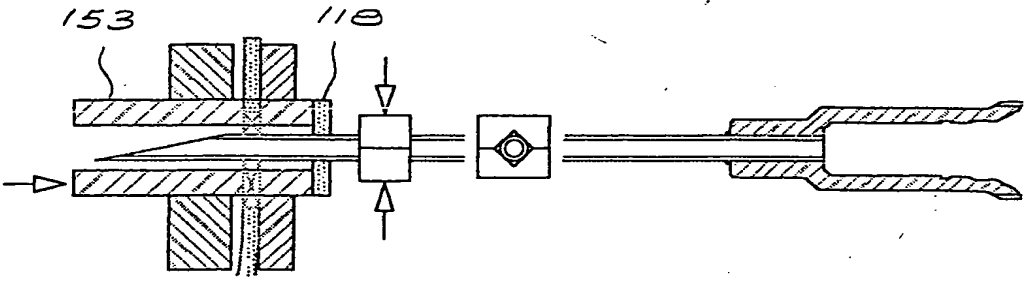


FIG 7C

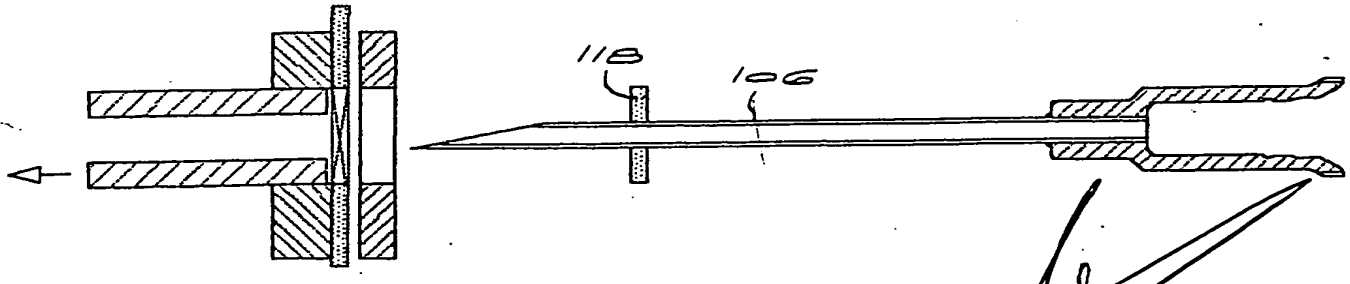


FIG 7D

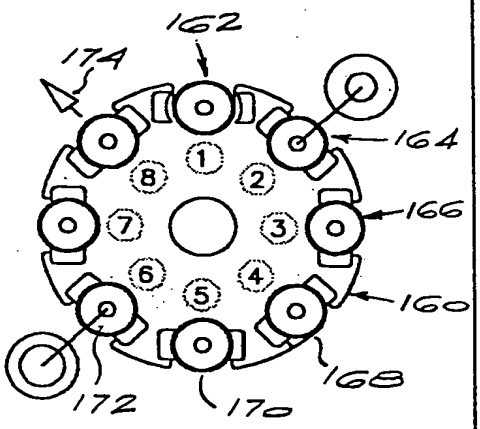


FIG 8A

FIG 8B

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